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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,322	03/12/2004	Robert James	17530	2289

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EXAMINER	
WONG, JENNIFER SHIN SHIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,322	JAMES ET AL.	
	Examiner	Art Unit	
	Jennifer Wong	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33 , drawn to drawn to methods to determine the onset or predisposition to neoplasma by assaying for a set of sequences, classified in class 435, subclass 6.

II. Claims 34-63, and 82, drawn to nucleic acids and kits with said nucleic acids, classified in class 536, subclass 23.1.

III. Claims 64-77, and 82, drawn to proteins and kits with said proteins, classified in class 530, subclass 350.

IV. Claims 78-81, drawn to a method of treatment of inappropriate cell growth with nucleic acids, classified in class 574, subclass 44.

V. Claims 78-81, drawn to drawn to a method of treatment of inappropriate cell growth with proteins, classified in class 514, subclass 2.

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of

invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the proteins of invention IIII are not required to practice the methods of invention I.

Inventions I and IV and I and V are drawn to patentably distinct methods requiring the use of different reagents, involving different process steps and having different outcomes or objectives. The methods of invention I require nucleic acid probes or primers and involve performing hybridization or sequencing steps in order to accomplish the objective of detecting sequences as a means for identifying an individual susceptible to neoplasma. Invention IV involves the use of nucleic acids and involves administering said nucleic acid for a period of time sufficient in order to treat a patient with inappropriate cell growth, whereas Invention V involves the use of proteins and involves administering said proteins for a period of time sufficient in order to treat a patient with inappropriate cell growth. The methods of invention I and IV, and I and V patentably distinct.

Inventions II and III are patentably distinct in structure and physicochemical properties. Inventions II is drawn to nucleic acids whereas inventions III is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional

properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention III do not require the particular products of the nucleic acids of invention II since the proteins can be isolated from natural sources or chemically synthesized.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, the nucleic acids of invention II are not required to practice the methods of invention V.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, the proteins of invention III are not required to practice the methods of invention IV.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the proteins of invention III can be used in a materially different process such as ligand binding assays or generate antibodies.

Inventions IV and V are drawn to patentably distinct methods, having different process steps, involving the use of different reagents and having different objectives. Invention IV involves the use of nucleic acid sequences and involves administering said nucleic acid sequences for a period of time sufficient in order to treat a patient with inappropriate cell growth, whereas Invention V involves the use of proteins and involves administering said proteins for a period of time sufficient in order to treat a patient with inappropriate cell growth. The methods of invention IV and V are patentably distinct.

2. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-V require different searches that are not co-extensive. For instance, a literature and sequence search for the methods of predicting a neoplasma of invention I is not co-extensive with a literature and sequence search for the nucleic acids of invention II or the proteins invention III or a search for the methods of treatment of inventions IV and V. Additionally, a finding that the method of

invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the nucleic acids of invention II, proteins of invention III, or methods of inventions IV and V were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the nucleic acids of invention II, proteins of invention III, or methods of inventions IV and V also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Restriction Requirement Applicable to Groups I, II, and IV:

3. The claims are drawn to a combination of genes, namely one or more genes. A restriction is applied to each Group. Each group detailed above reads on patentably distinct sequence of nucleic acid sequence. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each group.

For an elected group drawn to a nucleic acid sequence, the applicant must further elect a single nucleic acid sequence or a SPECIFIC combination of nucleic acid sequence. Applicant is further required to distinctly point out the location in the drawings, figures, or SEQ IDs of the instant application to which the elected sequence is drawn. Please include in the election of sequence or specific combination of sequence

the SEQ ID(s), the genebank numbers(s) (or any other identifier), the table or figure number, and the row or column location in the table. This is NOT an election of species.

Each of the different nucleic acid sequence is distinct from one another. Additionally, a reference which renders obvious a single gene, or combination thereof, will not necessarily also render obvious a different gene, or combination thereof. Similarly, a search indicating that a single gene, or combination thereof, is novel or unobvious will not necessarily also render novel or unobvious a different protein or combination thereof

Nucleotide sequences are structurally, chemically, and functionally distinct from one another as each sequence consists of unique nucleotide sequences. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

Restriction Requirement Applicable to Groups III and V:

4. The claims are drawn to a combination of proteins, namely one or more proteins. A restriction is applied to each Group. Each group detailed above reads on patentably distinct amino acid sequence. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each group.

For an elected group drawn to a protein, the applicant must further elect a single protein or a SPECIFIC combination of proteins. Applicant is further required to distinctly point out the location in the drawings, figures, or SEQ IDs of the instant application to which the elected sequence is drawn. Please include in the election of sequence or specific combination of sequence the SEQ ID(s), the genebank numbers(s) (or any other identifier), the table or figure number, and the row or column location in the table. This is NOT an election of species.

Each of the different protein is distinct from one another. Additionally, a reference which renders obvious a single protein, or combination thereof, will not necessarily also render obvious a different protein, or combination thereof. Similarly, a search indicating that a single protein, or combination thereof, is novel or unobvious will not necessarily also render novel or unobvious a different gene, or combination thereof, or protein or combination thereof.

Proteins comprise unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such protein sequence are presumed to represent an independent and

distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. A telephone call was made to Leopold Presser on April 5, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Wong whose telephone number is (571) 272-1120. The examiner can normally be reached on Monday-Friday; 8 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Wong

JEANINE A. GOLDBERG
PRIMARY EXAMINER
4/12/06